1648

D-2939CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

24 Election ex 7/25/01

In re application of:
Williams et al.

Serial No. 08/704,159

Filed: August 28, 1996

For: Multivalent Vaccine for Clostridium Botulinum Neurotoxin

Group Art Unit: 1648

Examiner: Bao Qun Li

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on or before July 2, 2001.

Jean F. Mueller

Title Patent Paralegal

Date July 2, 2001

RESPONSE TO OFFICE ACTION

Commissioner for Patents
Washington, DC 20231

Dear Sir:

This is in response to the Examiner's communication mailed May 31, 2001. In the communication, the Examiner is requiring restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

Group I: Claims 42-45, 54-65 and 79-109 drawn to a soluble recombinant protein, its associated fusion protein and a composition comprising the soluble protein, classified in class 424, subclass 247.1, class 435, subclass 252.7.

Group II. Claims 46-53, 66-78 drawn to a host cell expressing a recombinant protein encoded by Clostridium botulinum toxin classified in class 435, subclass 246.

The Examiner is also requesting that applicant elect a single disclosed protein sequence for prosecution on the merits. The Examiner has identified the following disclosed sequences.

(i) The recombinant protein is clostridium botulinum type A toxin;

(ii) The recombinant protein is clostridium botulinum type B toxin;

(iii) The recombinant protein clostridium botulinum type C1 toxin;

(iv) The recombinant protein clostridium botulinum type D toxin;

(v) The recombinant protein clostridium botulinum type E toxin;

(vi) The recombinant protein clostridium botulinum type F toxin;

(vii) The recombinant protein clostridium botulinum type G toxin;

(viii) The recombinant protein encoded by SEQ NO. 28;

(ix) The recombinant protein encoded by SEQ NO. 23;

(x) The recombinant protein encoded by SEQ NO. 40;

(xi) The recombinant protein encoded by SEQ NO. 42;

(xii) The recombinant protein encoded by SEQ NO. 46;

(xiii) The recombinant protein encoded by SEQ NO. 60;

(xiv) The recombinant protein encoded by SEQ NO. 66;

(xv) The recombinant protein encoded by SEQ NO. 50;

(xvi) The recombinant protein encoded by SEQ NO. 52;

(xvii) The recombinant protein encoded by SEQ NO. 71;

(xviii) The recombinant protein encoded by SEQ NO. 77;

(ixx) The recombinant protein encoded by SEQ NO. 68;
(xx) The recombinant protein encoded by SEQ NO. 73
(xxi) The recombinant protein encoded by SEQ NO. 79.
(xxii) The recombinant protein encoded by SEQ NO. 44.
(xxiii) The recombinant protein encoded by SEQ NO. 62.
(xxiv) The recombinant protein encoded by SEQ NO. 54.
(xxv) The recombinant protein encoded by SEQ NO. 56.
(xxvi) The recombinant protein encoded by SEQ NO. 26.

Applicant hereby elects the claims of Group I (i.e., claims 42-45, 54-65 and 79-109) with traverse. In addition, applicant elects to prosecute species (i) (Clostridium botulinum type A toxin) as identified by the examiner, with traverse. Applicant reserves the right to present additional species upon indication of an allowable generic claim.

Regarding the Restriction Requirement, 37 C.F.R. § 1.142 states that "[i]f two or more independent **and** distinct inventions are claimed in a single application, the Examiner ... will require the applicant ... to elect an invention to which the claims will be restricted". In addition, applicant also points out that under MPEP § 803, there are two criteria for a proper requirement for restriction, namely, (1) the invention must be independent or distinct, **and** (2) there must be serious burden on the Examiner for restriction to be required. Applicant respectfully contends that the requirements have not been met.

The Examiner contends that inventions (i) to (xxvi) are distinct because they are unrelated. The Examiner sites MPEP § 806.04, MPEP § 808.01 which states that inventions are unrelated if 1) it can be shown that they are not disclosed as capable of use together **and** 2) they have different modes of operation, different functions, or different effects. (February 26, 2001 Office Action, page 3). Page 36, lines 4 to 7 of the specification state that "The present invention further contemplates multi-valent vaccines comprising two or more

botulinal toxin proteins selected from the group comprising recombinant *C. botulinum* toxin proteins derived from serotypes A, B, C (including C1 and C2), D, E, F and G." Also, on page 30, lines 4 to 9 states that "In a still further preferred embodiment, the immunogen is a multivalent vaccine comprising the receptor-binding domain region of *C.* botulinum from two or more toxins selected from the group consisting of type A, type B, type C (including C1 and C2), type D, type E, and type F toxin." Therefore, the specification clearly states that the various serotypes and serotype fragments contained in sub-groups (i) to (xxvi) are capable of use together. Thus, the claimed protein sequences of the invention are not unrelated. Accordingly, the criteria for requiring the restriction has not been met.

Further, the second requirement of § 803 has not been met because the Patent Office has not demonstrated a serious burden for searching the art. The fact that the protein sequences of sub-groups (i- xxvi) are in the same class indicate that a search of the art would not place an undue burden on the Examiner. Moreover, separate prosecution of these claims would be unnecessarily duplicative and thus wasteful of Patent Office resources. Therefore, under MPEP § 803, the instant claims do not require restriction.

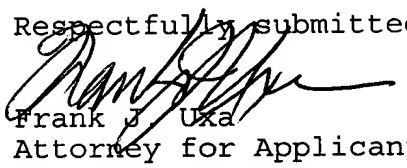
Applicant submits that sub-groups (i)- (xxvi) should be properly examined together for the reasons discussed above, and respectfully request the Examiner reconsider and withdraw the Restriction Requirement relating to sub-groups (i)- (xxvi).

Enclosed, please find a copy of an Associate Power of Attorney this application.

Please direct all future correspondence and telephone calls to:

Frank J. Uxa
4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764

Respectfully submitted,



Frank J. Uxa
Attorney for Applicant
Reg. No. 25,612
4 Venture, Suite 300
Irvine, CA 92618
(949) 450-1750
Facsimile (494) 450-1764